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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/050,848	01/18/2002	Norman G. Anderson	2315-148	3044

6449 7590 05/19/2003

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EXAMINER

LU, FRANK WEI MIN

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 05/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)	
10/050,848	ANDERSON ET AL	
Examiner	Art Unit	
Frank W Lu	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/23/2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) 7-10, 12, 14-17, 26-29, 31, 33-36, 45-48 and 52-55 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 18-25, 30 and 32 is/are allowed.
- 6) ☒ Claim(s) 1-6, 11, 13, 37-44, 49 and 51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 1/18/2002 (original) is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other.

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DETAILED ACTION

Response to Amendment

1. Applicant's response to the office action filed on January 23, 2003 has been entered. The claims pending in this application are claims 1-55 with claims 7-10, 12, 14-17, 26-29, 31, 33-36, 45-48, and 52-55 withdrawn from consideration as the result of the restriction requirement. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn based on amendment filed on January 23, 2003.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States

3. Claims 1-3, 6, 11, 13, 37, 39-41, 44, 49, and 51 are rejected under 35 U.S.C. 102(b) as being anticipated by Charlton *et al.*, (US Patent No. 4,106,907, published on August 15, 1978).

Charlton *et al.*, teach centrifuge tube and method for performing radio-immunoassay. As shown in Figure 1, centrifuge tube 1 with cylindrical shape comprised an upper region, a middle region and a low region wherein an inner diameter of said upper region was larger than an inner diameter of said middle region, wherein an inner diameter of said middle region was larger than an inner diameter of said low region, and wherein said lower region has a closed bottom as recited in (1) of claim 1 and claim 37 (for upper region, middle region, and lower region of a centrifugation

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tube taught by Charlton *et al.*, see attached Figure 1). Said inner diameter of said low region was $d=0.157$ inch ($d=4-6$ mm) and was 13.6% to 15.8% of the total length of said tube ($l/c=(7.5-15 \text{ mm})/(55-95 \text{ mm})$) as recited in claims 2, 3, 40, and 41 (see column 3). Note that: (1) since the specification does not give definition for ultracentrifuge tube, any regular centrifuge tube is considered as an ultracentrifuge tube as recited in claims 1 and 37; (2) since an inner diameter of the middle region of an ultracentrifuge tube is larger than an inner diameter of said lower region or the inner diameter of said middle region is the same as the inner diameter of said lower region wherein that inner diameter of the lower region and middle region having the same inner diameter is small enough to trap an air bubble between two layers of aqueous liquid such that the air bubble will keep said two layers of aqueous liquid separate so long as said ultracentrifuge tube is at rest, and wherein said lower region has a closed bottom, claim 1 is directed to two different ultracentrifuge tubes, the ultracentrifuge tube ((I) recited in claim 1) wherein the inner diameter of the middle region of the tube is larger than an inner diameter of said lower region is anticipated by Charlton *et al.*, (3) as shown in Figure 2, said upper region of the centrifuge tube had an outer diameter larger than an outer diameter of said low region as recited in claims 13 and 51.

Regarding claims 6 and 44, although Charlton *et al.*, did not directly show that the centrifuge tube could be centrifuged at velocities high enough to band viruses in CsCl gradient without said tube breaking, this limitation was considered as an intended use of the centrifuge tube taught by Charlton *et al.*, since a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable

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of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. *In re Casey*, 152 USPQ 235 (CCPA 1967); *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, applicant does not provide an evidence to show why the centrifuge tube taught by Charlton *et al.*, can not be centrifuged at velocities high enough to band viruses in CsCl gradient.

Regarding claims 11 and 49, although Charlton *et al.*, did not directly show that the centrifuge tube was made of polycarbonate, Charlton *et al.*, taught that the centrifuge tube was made of any organic plastic material (see column 2, lines 37-39).

Therefore, Charlton *et al.*, teach all limitations recited in claims 1-3, 6, 11, 13, 37, 39-41, 44, 49, and 51.

Response to Arguments

In page 3, last paragraph bridging to page 5, third paragraph of applicant's remarks, applicant argues that: (1) Charlton *et al.*, do not "teach, disclose, or suggest an ultracentrifuge tube in which an inner diameter of an upper region is larger than an inner diameter of a middle region, and either (i) an inner diameter of the middle region is larger than an inner diameter of a lower region or (ii) the inner diameter of the middle region is the same as the inner diameter of the lower region, as recited in amended claim 1. In Charlton, rather, two regions (zone 2 and zone 3 respectively in Fig. 1) are shown connected by a taper. A tapered region has no diameter, per se."; (2) "the claims recite an 'ultracentrifuge' tube. The tubes used in Charlton are centrifuge tubes. This is a significant difference because conventional centrifuge tube cannot be used for ultracentrifugation because they crush under the higher g forces."; and (3) "[C]harlton describes

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centrifuging the tubes at 1000g at column 2, line 46 and column 6, line 35. Ultracentrifugation, in contrast, is generally in the hundreds of thousands of g. The materials and design used to make ultracentrifuge tubes is generally different from those used for centrifuge tubes.”.

These arguments have been fully considered but they are not persuasive toward the withdrawal of the rejection. First, the examiner agrees with applicant that Charlton *et al.*, do not teach an ultracentrifuge tube wherein the inner diameter of the middle region is the same as the inner diameter of the lower region as recited in claim 1. However, Charlton *et al.*, discloses an ultracentrifuge tube wherein an inner diameter of an upper region is larger than an inner diameter of a middle region as recited in claim 1 (for upper region, middle region, and lower region of a centrifugation tube taught by Charlton *et al.*, see attached Figure 1). Second, although “[A] tapered region has no diameter, per se.”, the tapered region does not affect the inner diameter of the lower region of the centrifuge tube taught by Charlton *et al.*. Third, the examiner agrees with applicant that “[T]his is a significant difference because conventional centrifuge tube cannot be used for ultracentrifugation because they crush under the higher g forces”. However, since the specification does not give definition for ultracentrifuge tube, any regular centrifuge tube is considered as an ultracentrifuge tube. Furthermore, applicant does not show that there is a structural difference between the ultracentrifuge tube as recited in claim 1 and the centrifugation tube taught by Charlton *et al.*. Fourth, the examiner notes that Charlton *et al.*, describes centrifuging the tubes at 1000g at column 6, line 35. However, applicant does not provide an evidence to show why the centrifugation tube taught by Charlton *et al.* can not be considered as an ultracentrifuge tube.

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Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claim 4 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Charlton *et al.*, as applied to claims 1-3, 6, 11, 13, 37, 39-41, 44, 49, and 51 above, and further in view of Simmonds *et al.*, (US Patent No. 4,260,873, published on April 7, 1981).

The teachings of Charlton *et al.*, have been summarized previously, *supra*.

Charlton *et al.*, do not disclose to polish the inner surfaces of a centrifuge tube using vapor polishing as recited in claims 4 and 42.

Simmonds does teach to polish the inner surfaces of a centrifuge tube using vapor polishing (see columns 1 and 2).

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Therefore, in the absence of an unexpected result, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have used a vapor polishing agent to polish the inner surfaces of a centrifuge tube in view of the patent of Simmonds. One having ordinary skill in the art would have been motivated to polish the inner surfaces of a centrifuge tube described by Charlton *et al.*, because vapor polishing would remove oxidized plastic, dissolve uncovered plastic in a centrifuge tube, and make a smooth inner surface of the centrifuge tube (see Simmonds *et al.*, column 1). One having ordinary skill in the art at the time the invention was made would have been a reasonable expectation of success to polish the inner surfaces of a centrifuge tube using vapor polishing.

6. Claims 5 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Charlton *et al.*, as applied to claims 1-3, 6, 11, 13, 37, 39-41, 44, 49, and 51 above, and further in view of Saunders *et al.*, (US Patent No. 5,550,060, published on August 27, 1996).

The teachings of Charlton *et al.*, have been summarized previously, *supra*.

Charlton *et al.*, do not disclose a centrifuge tube whose inner surfaces are coated with an adhering polymer as recited in claims 5 and 43.

Saunders *et al.*, do teach to coat the inner surfaces of a centrifuge tube with an adhering polymer (see columns 11 and 12).

Therefore, in the absence of an unexpected result, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have coated the inner surfaces of a centrifuge tube with an adhering polymer in view of the patent of Saunders *et al.*

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One having ordinary skill in the art would have been motivated to modify the centrifuge tube described by Charlton *et al.*, because a centrifuge tube having an inner surface coating would improve cell separation result (see Saunders *et al.*, second paragraph in column 6 and claim 1 in column 16). One having ordinary skill in the art at the time the invention was made would have been a reasonable expectation of success to coat the inner surfaces of a centrifuge tube with an adhering polymer.

Response to Arguments

In page 8, first paragraph bridging to page 12, first paragraph of applicant's remarks, applicant argues that Charlton *et al.*, do not "teach, disclose, or suggest an ultracentrifuge tube in which an inner diameter of an upper region is larger than an inner diameter of a middle region, and either (i) an inner diameter of the middle region is larger than an inner diameter of a lower region or (ii) the inner diameter of the middle region is the same as the inner diameter of the lower region."

These arguments have been fully considered but they are not persuasive toward the withdrawal of the rejection. First, the examiner agrees with applicant that Charlton *et al.*, do not teach an ultracentrifuge tube wherein the inner diameter of the middle region is the same as the inner diameter of the lower region as recited in claim 1. However, Charlton *et al.*, discloses an ultracentrifuge tube wherein an inner diameter of an upper region is larger than an inner diameter of a middle region as recited in claim 1 (for upper region, middle region, and lower region of a centrifugation tube taught by Charlton *et al.*, see attached Figure 1).

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Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-6, 11, 13, 37-44, 49, and 51 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 6,254,834. Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claims in this instant application is either anticipated by, or would have been obvious over, the reference claims. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164

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USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

Although claims 1-6, 11, 13, 18-25, 30, 32, 37-44, 49, and 51 in this instant application are not identical to claims 1-25 of US Patent No. 6,254,834, claims 1-25 in US Patent No. 6,254,834 are directed to the same subject matter and fall entirely within the scope of claims 1-6, 11, 13, 37-44, 49, and 51 in this instant application. In other words, claims 1-6, 11, 13, 37-44, 49, and 51 in this instant application are anticipated by claims 1-25 of US Patent No. 6,254,834. For example, claim 1 of this instant application has much broader than claim 1 of US Patent No. 6,254,834 and claim 1 of US Patent No. 6,254,834 has all limitations of claim 1 of this instant application (the ultracentrifuge tube (I), not the ultracentrifuge tube (ii)). Claim 37 of this instant application has much broader than claim 16 of US Patent No. 6,254,834 and claim 16 of US Patent No. 6,254,834 has all limitations of claim 37 of this instant application. Claims 2-6, 11, 13, of this instant application are identical to claims 3-6, 8, 9, and 11 of US Patent No. 6,254,834 respectively while 38-44, 49, and 51 of this instant application are identical to claims 2, 21, 18, 17, 19, 20, 9, and 11 respectively.

Response to Arguments

In page 12, third paragraph of applicant's remarks, applicant argues that "M.P.E.P. § 804(II)(B)(1) requires that an obviousness-type double patenting rejection make clear the reasons why a person of ordinary skill in the art would conclude that the invention defined in the claim at issue is an obvious variation of the invention defined in the patent. The Applicant requests respectfully that the Office Action do so."

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In previous office action, the examiner made clear "the reasons why a person of ordinary skill in the art would conclude that the invention defined in the claim at issue is an obvious variation of the invention defined in the patent". However, in order to address applicant's arguments and make the office action more clear, the examiner has added more detailed rejection in this office action (see above).

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Claims 18-25, 30, and 32 are allowed over prior art.

11. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal

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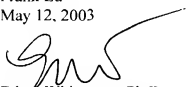
Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (703) 305-1270. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the patent Analyst of the Art Unit, Ms. Chantac Dessau, whose telephone number is (703) 605-1237.

Frank Lu
May 12, 2003



Ethan Whisenant, Ph.D.
Primary Examiner (FSA)